July 18, 2006

Glenn S. Simon, Ph.D., DABT
Technical Contact
Rhodia Inc.
5171 Glenwood Avenue
Suite 402
Raleigh, NC 27612

Dear Dr. Simon:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Tris(2-chloroethyl) phosphite, posted on the ChemRTK HPV Challenge Program Web site on March 30, 2005. I commend Rhodia Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Rhodia advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Tris(2-chloroethyl) Phosphite

Summary of EPA Comments

The sponsor, Rhodia Inc., submitted a test plan and robust summaries to EPA for Tris(2-chloroethyl) phosphite (T2CEP, CAS No. 140-08-9) dated March 22, 2005. EPA posted the submission on the ChemRTK HPV Challenge Web site on March 30, 2005.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to provide measured data for the melting point, vapor pressure and water solubility endpoints. The submitter may need to indicate how the stability in water test results affect the water solubility and partition coefficient endpoint evaluations.

2. Environmental Fate. EPA agrees with the submitter's proposed testing for stability in water. The submitter needs to provide measured ready biodegradation data on T2CEP.

3. Health Effects. EPA agrees with the submitter's proposed testing for developmental toxicity. The submitter also needs to provide data for the chromosomal aberrations endpoint. The information provided in the test plan does not satisfy the requirements for classifying T2CEP as a "closed system intermediate" (CSI) meriting reduced testing. Unless additional information is provided to support the CSI claim, the submitter needs to address all health effects endpoints for the purposes of the HPV Challenge Program.

4. Ecological Effects. Adequate data were submitted for these endpoints for the purposes of the HPV Challenge program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Tris(2-chloroethyl) Phosphite
Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The submitted data for boiling point are adequate for the purposes of the HPV Challenge Program.

Melting point. The submitted calculated melting point value is not adequate because values above 0 °C should be measured for the purposes of the HPV Challenge Program. The submitter needs to provide measured melting point data. Data from published sources are acceptable as long as the submitter provides the source.

Vapor pressure. The submitted vapor pressure value of 0.13 hPa at 20 °C provided no method or original source, while the handbook value of <1.33 hPa at 20 °C is only an upper limit. The calculated value of 0.000405 hPa (4.05×10^{-2} Pa) at 25 °C is not adequate because calculated values over 1×10^{-5} Pa are not acceptable for the purposes of the HPV Challenge Program. The submitter needs to provide measured vapor pressure data following OECD TG 104. Alternatively, an estimated vapor pressure at 20°C should be obtainable in this case by extrapolation of the boiling points at various pressures given in the boiling point robust summary.

Water solubility. The submitter provided an estimated water solubility value of 951 mg/l at 25 °C. Estimated values above 1 µg/L are not adequate for the purposes of the HPV Challenge Program. However, the submitter also indicates that it will provide measured hydrolysis data. If the chemical hydrolyzes slowly or is stable, then the submitter needs to provide measured water solubility data following OECD TG 105. On the other hand, if this chemical hydrolyzes at a rate making it difficult or infeasible to measure water solubility, then the submitter needs to incorporate this information in the water solubility robust summary.

Octanol/water partition coefficient. The calculated Log Kow value provided by the submitter may be adequate for the purposes of the HPV Challenge Program. The submitter indicates that measured hydrolysis data will be provided. If the chemical hydrolyzes slowly or is stable, then the value provided will be adequate. On the other hand, if this chemical hydrolyzes rapidly, then the implications of this information for the Log Kow endpoint need to be stated in the robust summary.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for photodegradation and fugacity are adequate for the purposes of the HPV Challenge Program.

Stability in water. EPA agrees with the submitter's proposal to conduct a hydrolysis test for T2CEP following OECD TG 111. The hydrolysis products should be identified (see Biodegradation below).

Biodegradation. The submitter indicated in the test plan that tris(2-chloroethyl) phosphite is not expected to be readily biodegradable on the basis of data for a structurally-similar compound, triethyl phosphite. However, a review of the submitter's source provided data indicating that triethyl phosphite could be biodegradable according to EPA guidelines. Further, EPA-located data from a Zahn-Wellens test indicate that the ester triethyl phosphate is >90% biodegradable after 7 days (Verschueren K. 1996. Handbook of Environmental Data on Organic Chemicals, 3rd Edition. NY: Van Nostrand Reinhold). Because the presence of chlorine groups in T2CEP may slow biodegradation in comparison with triethyl phosphate, the submitter needs to provide measured ready biodegradation data either for T2CEP (if the hydrolysis data show slow or no hydrolysis) or for its hydrolysis products (if T2CEP hydrolyzes rapidly).

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for the acute toxicity and gene mutation endpoints.

Chromosomal aberration. The submitted data for a mitotic recombination test (OECD 481) are not adequate to address this endpoint because this test detects non-specific DNA damage (gene conversion and crossing over) but not specific chromosomal defects (e.g., aberrations). Therefore, the submitter needs to conduct an *in vitro* chromosomal aberration test according to OECD TG 473.

Repeated-dose toxicity and reproduction toxicity. The submitter proposes an exemption from testing for these endpoints based on its claim that T2CEP is a closed-system intermediate. The information provided by the submitter is not adequate to satisfy the requirements for classification as a CSI under the HPV Challenge Program.

The Guidance for Testing Closed System Intermediates for the Challenge Program (http://www.epa.gov/chemrtk/guidocs.htm) allows for a reduced testing proposal provided certain criteria are met. The information required to judge a CSI claim must address the following:

I. Site Information
   A. Number of sites.
   B. Basis for "closed process" conclusion at each site.
   1) Process description
   2) Monitoring data showing no detection.

3) In the absence of monitoring data, the basis for believing that releases do not occur.
C. Data on "presence in distributed products."

II. Information on transport (mode, volume, controls, etc); and
III. A data search showing that the chemical is not present in other end-products.

Basis for closed process conclusion at each site: according to the test plan, T2CEP is produced in two reactors connected in series by steel piping. The T2CEP product is then piped into a 600 gallon tank which feeds the chemical into a downstream product reactor where T2CEP is consumed.

A small amount of T2CEP (about 0.1% of total production) is packaged in steel drums and sold to customers. Use of T2CEP by the customer is not described. Information on the basis for use in a closed process by the customer or an indication of why this information is not available is needed to satisfy the information requirement for a closed process at each site.

If transport occurs, information on the mode of transport, volume, type of consignment, and controls during transport and transfer at dispatching and receiving sites: T2CEP is packed in steel drums for sale to 1 to 2 industrial customers. The volume of T2CEP sold to others is about 0.1% of total production. According to the test plan, "The drumming equipment is equipped with exhaust ventilation"; additional information should be provided on the exhaust system and on the disposition of the exhausted vapors. Information is not provided on the handling of T2CEP by the customer; information on handling and controls at the receiving site is needed to satisfy this requirement.

Supporting evidence that the chemical is not present in other end-products: The test plan does not provide any supporting evidence that T2CEP is not present in any other end-products. This requirement could be satisfied by the additional explanation of the consumption of all T2CEP in the first and subsequent reactions as an intermediate used on-site plus evidence that T2CEP is not present in end-products produced by customers.

Unless additional information is provided to support the CSI claim, the submitter needs to address these endpoints for the purposes of the HPV Challenge Program (see next paragraph).

Developmental toxicity. Although EPA agrees with the submitter's proposed testing for developmental toxicity according to OECD TG 421 (reproductive/developmental toxicity screening test), if the CSI claim cannot be further substantiated, EPA recommends that the repeated-dose/reproductive/developmental toxicity endpoints be addressed with the combined screening study OECD TG 422.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the submitter that the acute toxicity data for fish and daphnia are adequate for the purposes of the HPV Challenge program. While the submitter proposed conducting an algal test, EPA concludes that the body of available analog data is sufficient to characterize algal toxicity as well.

Specific Comments on the Robust Summaries

None.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.